

We Claim:

1. A method of preparing a microfluidized lysate preparation comprising microfluidizing a slurry of at least one *Leishmania* parasite through a chamber and disrupting the leishmania parasite with a sudden release of pressure.
2. The method of claim 1, further comprising heat treating the microfluidized lysate preparation.
3. The method of claim 1, wherein the *Leishmania* parasite is *L. tropica*, *L. mexicana*, *L. guyanensis*, *L. braziliensis*, *L. major*, *L. donovani*, *L. chagasi*, *L. amazonensis*, *L. peruviana*, *L. panamensis*, *L. pifanoi*, *L. infantum*, or *L. aethiopica*.
4. A microfluidized lysate preparation made by the method of claim 1.
5. A skin test antigen assay for detecting whether a subject had been exposed to a *Leishmania* parasite or was afflicted with Leishmaniasis comprising administering to the subject an antigenic amount of at least one microfluidized lysate preparation according to claim 4 and observing any immunogenic response to the microfluidized lysate preparation.
6. The skin test antigen assay of claim 5, wherein the *Leishmania* parasite is *L. tropica*, *L. mexicana*, *L. guyanensis*, *L. braziliensis*, *L. major*, *L. donovani*, *L. chagasi*, *L. amazonensis*, *L. peruviana*, *L. panamensis*, *L. pifanoi*, *L. infantum*, or *L. aethiopica*.
7. The skin test antigen assay of claim 5, wherein an immunogenic response indicates that the subject had been exposed to a *Leishmania* parasite or was afflicted with Leishmaniasis.
8. The skin test antigen assay of claim 5, wherein an induration of about 5 mm or greater observed indicates that the subject had been exposed to a *Leishmania* parasite or was afflicted with Leishmaniasis.

9. The skin test antigen assay of claim 5, wherein the antigenic amount of the microfluidized lysate preparation comprises about 5 µg to about 30 µg of total protein.

10. The skin test antigen assay of claim 5, wherein the antigenic amount of the microfluidized lysate preparation is administered intradermally to the volar surface of the forearm of the subject.

sub AI 11. A kit comprising the microfluidized lysate preparation of claim 4 and directions for determining whether a subject has been exposed to a *Leishmania* parasite or was afflicted with Leishmaniasis.

12. The kit of claim 11, wherein the *Leishmania* parasite is *L. tropica*, *L. mexicana*, *L. guyanensis*, *L. braziliensis*, *L. major*, *L. donovani*, *L. chagasi*, *L. amazonensis*, *L. peruviana*, *L. panamensis*, *L. pifanoi*, *L. infantum*, or *L. aethiopica*.

13. The kit of claim 11, further comprising at least one pharmaceutical for treating systemic anaphylaxis.

14. The kit of claim 13, wherein the pharmaceutical is epinephrine, diphenhydramine, or methyl prednisolone.

15. The kit of claim 11, further comprising at least one pharmaceutical for treating local reactions to the microfluidized lysate preparation.

16. The kit of claim 15, wherein the pharmaceutical is hydrocortisone, hydrocortisone cream, acetaminophen, or diphenhydramine.

17. An antibody raised against the microfluidized lysate preparation of claim 4.

sub AI 18. A vaccine comprising the microfluidized lysate preparation of claim 4.

19. A method of determining whether a subject has been exposed to a given *Leishmania* parasite comprising administering to the subject a panel of antigenic compositions

comprising a plurality of microfluidized lysate preparations prepared from a plurality of *Leishmania* parasites and detecting a presence of an immunogenic reaction that is characteristic to exposure to the given *Leishmania* parasite.

20. The method of claim 19, wherein the plurality of *Leishmania* parasites comprises at least one parasite from the group consisting of *L. tropica*, *L. mexicana*, *L. guyanensis*, *L. braziliensis*, *L. major*, *L. donovani*, *L. chagasi*, *L. amazonensis*, *L. peruviana*, *L. panamensis*, *L. pifanoi*, *L. infantum*, and *L. aethiopica*.

21. A method of immunizing a subject against Leishmaniasis comprising administering to the subject an immunogenic amount of the microfluidized lysate preparation of claim 4.

22. A pharmaceutical composition comprising the microfluidized lysate preparation of claim 4 and a pharmaceutically acceptable stabilizer.

23. The pharmaceutical composition of claim 22, wherein the pharmaceutically acceptable stabilizer is phenol.

24. The pharmaceutical composition of claim 22, wherein the composition is in the form of a liquid.

25. The pharmaceutical composition of claim 22, wherein the composition may be frozen or freeze-dried.

26. A method for determining post infection of cutaneous leishmaniasis, mucocutaneous leishmaniasis, or post-kala-azar dermal leishmaniasis in a subject comprising administering to the subject an antigenic amount of at least one microfluidized lysate preparation of claim 4 and observing any immunogenic response to the microfluidized lysate preparation.

27. A method for epidemiologically diagnosing cutaneous leishmaniasis, mucocutaneous leishmaniasis, or post-kala-azar dermal leishmaniasis in a subject comprising

administering to the subject an antigenic amount of at least one microfluidized lysate preparation of claim 4 and observing any immunogenic response to the microfluidized lysate preparation.

28. A method for determining the pattern of present and past leishmaniasis in a subject comprising administering to the subject an antigenic amount of at least one microfluidized lysate preparation of claim 4 and observing any immunogenic response to the microfluidized lysate preparation.

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